K090172

JUN – 5 2009

LARSEN & TOUBRO LIMITED

ELECTRONICS DIVISION ELECTRONIC PRODUCTS

Regd. Office: KIADB Industrial Area, Hebbal, Hootagalli, Mysore - 570 018 • Tel: +91(821)2402561 • Fax: +91(821)2402468

510(K) SUMMARY

(Per section 807.92 ©)

CONTACT DATA			
Submitter's Name		Larsen & Toubro Limited	
Address		KIADB Industrial Area, Hebbal Hootagalli, Mysore – 570018, Karnataka, INDIA	
Telephone	91-821-2402561	**Fax**	91-821-2402468
Contact Person	A.B.Deshpande	**Title**	Head – Quality Assurance & Management Representative
E-Mail address		DeshpandeAB@myw.ltindia.com	
Date the summary was prepared		20th Apr 2009	

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LARSEN & TOUBRO LIMITED

ELECTRICAL & ELECTRONICS DIVISION ELECTRONICS [illegible]

DEVICE	
Trade name	STAR 55 *Model 100*
Common name	Patient Monitoring System
Classification name	Vital Signs Monitor

PREDICATE DEVICE IDENTIFICATION			
CFR21 Section	870.1025	**Product code (optional)**	MHX
Classification panel		Cardiovascular	
Device Class		Class II	
Legally marketed Comparison Device / K#		• STAR 55 Patient Monitoring System (L&T Medical Equipments & Systems) / K080173 • Passport 2 Vital signs monitor with View 12 ECG Analysis Module (Datascope Corp.) / K020550	

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DEVICE DESCRIPTION

STAR 55 *Model 100* is a multi-parameter patient monitoring system for continuous monitoring of the physiological parameters ECG (3/5/12 lead), Arrhythmia & ST analysis, Respiration, NIBP, IBP, Temperature, SpO2, CO2 & Gas monitoring.

STAR 55 *Model 100* is a 8-channel monitor with 12.1" TFT display capable of displaying ECG, Respiration, SpO2, CO2, digital values of HR/PR, SpO_2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, $EtCO_2$, $FiCO_2$, N_2O, O_2, EtAA and FiAA readings. It has selective 24\48\72 Hours tabular and graphical trends. It has special feature of NIBP having a trend of storing last 240 readings. It has Alarm Recall facility with last 24 patient alarms details. It has a two-channel thermal array recorder for printing of Tabular trends & waveforms. It has got optional communication features – USB, RS232, Infrared remote and Ethernet. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals.

INTENDED USE OF THE DEVICE

The STAR 55 *Model 100* multi-parameter Patient Monitoring system is intended to monitor a single Adult, Pediatric or Neonatal patient's vital signs at the bedside or during intra-hospital transport along with the appropriate accessories mentioned / supplied with the unit. Vital signs parameters include ECG (3 lead /5 lead/ 12 lead), SpO2, Respiration, Temperature, Capnography (CO_2) & optional Gas module unit. It can also display the digital values of HR/PR, SpO_2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, $EtCO_2$, $FiCO_2$, N_2O, O_2, EtAA and FiAA readings.
In addition Star 55 Model 100 has got Arrhythmia and ST detection from 3L/5L/12L ECG measurements. The Arrhythmia and ST analysis module is intended for use with Adult & Pediatric patients and is not intended for use with Neonatal patients.
The user, responsible to interpret the monitored data made available, will be a professional health care provider. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The monitor is not intended for home use.

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LARSEN & TOUBRO LIMITED

ELECTRICAL & ELECTRONICS DIVISION

Ref

Date: 20.04.2009

TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

Device: Larsen & Toubro limited make STAR 55 *Model 100* Patient Monitoring System.
Predicate device:

- STAR 55 Patient Monitoring System (L&T Medical Equipments & Systems) / K080173
- Passport 2 Vital signs monitor with View 12 ECG Analysis Module (Datascope Corp.) / K020550

The parameters available with the Larsen & Toubro Limited make STAR 55 *Model 100* Patient monitoring system are available with the predicate device Datascope Corp. make "Passport 2 Vital signs monitor with View 12 ECG Analysis Module" for 12 Lead ECG analysis & Larsen & Toubro Limited make STAR 55 Patient monitoring system for all other parameters.
The data acquired by 12L ECG Module is interpreted utilizing Mortara Instruments algorithm (cleared by FDA under notification numbers: K920627, K933143).

Comparison of all the parameters of STAR 55 *Model 100* to that of the predicate devices is given in the "Predicate device comparison table" document.

Compliance to standards:
The following international standards are referred.
IEC 60601-1 Medical Electrical safety
IEC 60601-1-2 EMC compliance

Conclusion:
Based on the Technological characteristics of STAR 55 *Model 100* and its comparison with that of predicate devices Larsen & Toubro Limited believes that their device is substantially equivalent to this predicate Monitors and doesn't pose any additional risk on safety & effectiveness of the device.

(N Ravindran)
Head – Design & Development

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2009

Larsen & Toubro Limited
c/o Ms. Yolanda Smith
Smith Associates
1468 Harwell Ave.
Crofton, MD 21114

Re: K090172
Trade/Device Name: Star 55 Model 100
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: May 6, 2009
Received: May 7, 2009

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090172

Indications for Use

510(k) Number (if known) K090172

Device name: **STAR 55 *Model 100***

Indication for use:

The STAR 55 *Model 100* multi-parameter Patient Monitoring system is intended to monitor a single Adult, Pediatric or Neonatal patient's vital signs at the bedside or during intra-hospital transport along with the appropriate accessories mentioned / supplied with the unit. Vital signs parameters include ECG (3 lead /5 lead/ 12 lead), SpO2, Respiration, Temperature, Capnography (CO_2) & optional Gas module unit. It can also display the digital values of HR/PR, SpO_2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, EtCO2, $FiCO_2$, N_2O, O_2, EtAA and FiAA readings.
In addition, Star 55 Model 100 has got Arrhythmia and ST detection from 3L/5L/12L ECG measurements. The Arrhythmia and ST analysis module is intended for use with Adult & Pediatric patients and is not intended for use with Neonatal patients

The user, responsible to interpret the monitored data made available, will be a professional health care provider. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The monitor is not intended for home use.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The –Counter Use ____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Volmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090172